National Environmental Laboratory **Accreditation** Conference

nelac

Program Policy and Structure

Proposed Changes

January 12, 1998

1.1 INTRODUCTION

1.1.1 Overview of NELAC

This association shall be known as the "National Environmental Laboratory Accreditation Conference" (NELAC) and is sponsored by the United States Environmental Protection Agency (EPA) as a voluntary association of state and federal officials. The purpose of the organization is to foster the generation of environmental laboratory data of known and documented quality in a cost-effective manner through the development of nationally accepted standards for environmental laboratory accreditation. NELAC encompasses all fields of testing associated with compliance with EPA regulations. The program will be administered by state and federal accrediting authorities in a uniform, consistent fashion nationwide.

1.1.3 Summary of the NELAC standards

The NELAC uniform standards. . .

The Field Measurements and Sampling Committee standards which are to be developed will require that sampling be done using a documented quality system, which is appropriate to the type, range, and scope of sampling.

1.1.4 General application of NELAC standards

These standards are for use by accrediting authorities and others concerned with the competence of environmental laboratories and other organizations directly involved in environmental measurements. Note that any reference to NELAP approval or ~~NELAP~~ NELAC accreditation means that the accrediting authority or laboratory meets the requirements in the NELAC standards, and is not endorsement by EPA.

An accredited laboratory may use the NELAC logo on general literature in conjunction with the phrase *meets NELAC standards*. It is the ethical responsibility of an accredited organization to describe its accredited status in a manner that does not imply accreditation in areas that are outside their actual Scope of Accreditation. When soliciting business or reporting test results, an accredited entity must distinguish between those tests that fall within its scope of accreditation and those that do not. This is done by attaching a copy of its current NELAC Scope of Accreditation and any other appropriate supplement.

1.1.5 Application of NELAC standards to small laboratory operations

All laboratory operations subject to NELAC standards are expected to generate data of known and documented quality and maintain the quality systems required to generate quality data. However, NELAP recognizes that some laboratory operations have some unique characteristics that differentiate them from other operations. The NELAC standards have addressed these issues by allowing some flexibility in meeting the requirements for personnel (Section 5.4.2, Section 5.6) and their credentials (Section 4.1.1).

1.3 ELEMENTS

Functional elements of the objectives are:

e) To incorporate, to the extent applicable, ISO 25, ISO 43, and ISO 58.[1] ~~NOTE: A review by the Environmental Laboratory Advisory Board (ELAB), a federal advisory committee, is currently underway on whether to include within NELAC, laboratories complying with Good Laboratory Practices (GLP). GLPs are mandated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). If GLP laboratories are included in NELAC, the EPA GLP programs and the Organization for Economic and Cooperative Development (OECD) GLP Principle Technical Standards will be incorporated, to the extent applicable.~~

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~~**1.5 NELAC PARTICIPANTS**~~

~~The participants of NELAC shall be from the States and federal agencies, the organizations subject to accreditation under the standards of NELAC and other interested groups (see Section 1.7.4).~~

1.5~~6~~ ROLES AND RESPONSIBILITIES OF THE FEDERAL GOVERNMENT, THE STATES, AND OTHER PARTIES

1.5~~6~~.1 EPA

EPA shall provide staff support to NELAC as provided for in the Bylaws and agreed to by EPA. EPA shall assist NELAC by ~~providing all proposed and final standards and~~ publishing all proposed and final standards ~~on the NELAC electronic bulletin board~~.

EPA also participates in joint activities with other federal and State agencies, as described below.

1.5~~6~~.2.3 Accrediting authorities

An accrediting authority can be either a) any federal department/agency with responsibility for operating mandated environmental monitoring programs which require laboratory testing, or b) any State which requires laboratory testing in conformance with at least one of the EPA programs listed within the scope of NELAC (see Section 1.4.2). If a State chooses not to adopt ~~participate~~ in the NELAC program, laboratories in that State may obtain accreditation from any other accrediting authority.

A primary accrediting authority is one. . .

1.5~~6~~.2.3.1 Responsibilities of primary accrediting authorities

Once a State or federal department/agency has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of NELAC, it will be a primary accrediting authority, and it will have full responsibility . . .

In addition, a primary accrediting authority may. . .

1.5~~6~~.3 Reciprocity

Reciprocity means that an accrediting authority will recognize and accept the accreditation status of a laboratory issued by another NELAP accrediting authority. This principle of reciprocity is an element of the national accreditation standard to which all accrediting authorities are held. In recognizing the accreditation status of a laboratory through reciprocity, the accrediting authority assumes the responsibilities of a secondary accrediting authority as stated in Section 1.6.2.3.2. ~~However, a decision arising from a legal action within the jurisdiction of a secondary accrediting authority may prevent recognition and acceptance of the primary accreditation.~~ A state, in the role of a secondary accrediting authority, which has a law or decision resulting from a legal action, the legal effect of which precludes that state from granting any accreditation to a particular laboratory, is not required to extend reciprocity to that laboratory.

Reciprocity among the. . .

1.5~~6~~.5 Assessor Bodies

An assessor body, operating under written agreement with an accrediting authority, may perform specified functions of the assessment process. These functions may include: the review of the laboratories' documentation regarding facilities, personnel, use of approved methods, and quality assurance procedures; and conduct of on-site assessments, including review of performance in the analysis of proficiency test samples. The assessor body reports ~~directly~~ to the accrediting authority under which it is operating. The assessor body will provide . . .

1.6~~7~~ STRUCTURE OF NELAC

1.6~~7~~.1 The Board of Directors

The Board of Directors consists of . . .

The Board of Directors serves as . . . The Board of Directors will charge the committees with issues they must address or take under ~~and may suggest other issues for committee~~ consideration. Comments on the standards should be directed to the committees through their respective chairs.

1.6~~7~~.2 The Environmental Laboratory Advisory Board

The Environmental Laboratory Advisory Board. . . The recommendations of the ELAB shall be presented to the Chairs of the standing committees, the Board of Directors and to the EPA.

1.6~~7~~.5 The Committees

Two types of committee are associated with. . .

New Standing Committees:

The Board of Directors may create a new standing committee if the following conditions exist:

An ad hoc group appointee by a NELAC Chair has been studying an issue which is likely to require continuing attention by NELAC; the ad hoc has reached a consensus and is ready to develop standards and once implemented, the standards are likely to need evaluation and revision in the future; no NELAC committee exists to deal with the issue; the topic is of broad scope and has impact on a significant portion of the laboratory community; the Policy and Structure Committee has received the proposal and is satisfied that there is a need for the new committee, its purpose has been clearly stated, and there is a clear outline of the scope of the proposed committee's activities, and recommends that the new standing committee be created.

1.6~~7~~.5.1 The Standing Committees

The participants of each committee serve for five years, with one Voting Member and one Contributor being appointed each year. There are ~~seven~~ eight Standing Committees:

- Program Policy and Structure Committee
- Accrediting Authority Committee
- Quality Systems Committee
- Proficiency Testing Committee
- On-site Assessment Committee
- Accreditation Process Committee
- Implementation Committee
- Sampling and Field Measurement Committee.

The Standing Committees shall receive. . . These resolutions will be made available not less than 45 ~~30~~ calendar days prior to the annual meeting. All resolutions shall be. . . The committees shall draft resolutions which shall be made available not later than 30 calendar days prior to either the interim or annual meetings. The committees shall prepare and arrange agenda items for interim meetings and annual meetings to be made available 30 calendar days prior to the meeting.

1.6~~7~~.5.1.8 Sampling and Field Measurement Committee

This committee prescribes the standards for use in field measurements and sampling and coordinates the development of those standards with the other standing committees, including any requirements for training of field personnel.

1.7~~8~~ CONDUCT OF CONFERENCE BUSINESS

1.7~~8~~.1 The Generation of Standards

The process for the generation . . . Standards proposed by the committees are publicized on the NELAC electronic bulletin board by EPA not later than 45 ~~30~~ calendar days prior to the date of the meeting at which they will be considered.

Proposed amendments from the floor. . . Amendments to the report describing committee activities over the year will not be allowed without the concurrence of the chair~~man~~ of the subject committee and the concurrence of the Chair of NELAC.

1.7~~8~~.2 Meetings

1.7~~8~~.2.1 Annual Meeting

An annual meeting of NELAC shall. . .

The Board of Directors shall determine the place and dates for the annual meeting, after receiving recommendations from the Conference Management Committee, and shall publish this information on the NELAC electronic bulletin board at least 90 calendar days prior to the annual meeting.

A completed registration for the annual meeting shall. . .

The following deadlines will apply in preparing and submitting material for the annual meeting:

a) Sixty calendar days prior to the date of the annual meeting, each of the standing committees shall present to the Board of Directors a summary of the issues and matters considered by the committees over the course of the year. This report . . .

b) Committees shall prepare and arrange agenda items and resolutions for the annual meeting. These, and other resolutions received by the Board of Directors will be made available not less than 45 ~~30~~ calendar days prior to the meeting.

c) Standards proposed by the committees for consideration at the annual meeting shall be publicized on the electronic bulletin board not less than 45 ~~30~~ calendar days prior to the annual meeting.

As soon as possible, but no later than 90 calendar days after ~~Within 90 days following~~ the annual meeting, the Board of Directors shall make available an updated roster of the Board of Directors, NELAC officers, committee members and chairs, and minutes and findings of the meeting to the participants. EPA shall publish the ~~final~~ revised standards as soon as possible, but no later than 90 calendar days after ~~within 90 days following~~ the annual meeting. Changes in organization and/or procedures of NELAC proposed at the annual meeting shall not be acted upon until the annual meeting following the annual meeting at which proposed.

1.7~~8~~.2.2 Interim Meeting

The interim meeting, at which time committees meet to receive, consider and debate on issues, and propose and draft standards or policies for the annual meeting, shall be scheduled at least ~~approximately~~ six months prior to the annual meeting.

The Board of Directors shall determine the place and dates for the interim meeting, after receiving recommendations from the Conference Management Committee, and shall publish this information on the NELAC electronic bulletin board at least 90 calendar days prior to the interim meeting.

Committees shall prepare and arrange agenda items for the interim meeting. The agenda shall be approved by the Board of Directors and will be made available not less than 30 calendar days prior to the date of the meeting.

Conclusions and findings of the interim meeting shall be provided to the participants not later than 90 calendar days following the interim meeting.

1.8~~9~~ ORGANIZATION OF THE ACCREDITATION REQUIREMENTS

1.8~~9~~.1 Scope of Accreditation

Laboratories must meet all relevant EPA program requirements, including quality assurance/quality control, use of specified methods/analyte classes, and other criteria.

The accreditation requirements shall be based on the tiered approach shown in Figure 1-3. Laboratories must meet the general requirements found in Chapter 5, and the specific quality control requirements for the type of testing being performed, as found in Appendix D of Chapter 5. Accreditation will then be granted for compliance with the relevant EPA program, the methods used by the laboratory, and for individual analytes determined by a particular method/analyte class; e.g., a laboratory determining lead in drinking water, in compliance with the Safe Drinking water Act, by both inductively-coupled plasma mass spectrometry and graphite furnace atomic absorption spectrometry would be accredited for lead by both methods. Loss of accreditation for an analyte would not automatically result in loss of accreditation for all other analytes accredited under the method/analyte class, provided the laboratory remained proficient in the determination of the other analytes.

The following example shows . . .

The tiered approach eliminates . . . These processes, defined in Chapters 2 and 3, do not necessarily evaluate all tiers within the tiered structure; e.g., proficiency testing examines the determination of individual analytes in specific matrix types, and is not method/analyte class-specific. However, they are comprehensive enough to assure the accrediting authority that a system is in place that produces data of known and documented quality.

An accrediting authority may approve . . .